Section 2.0 510(k) Summary

MAR 8 2002

K013005
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2.1 Submitted by

InnerSpace
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Prepared Sept. 4, 2001

This submittal covers a modification to ACT II, 510(k) K010422. The modification adds the ability to insert a monitoring probe through the device and into the brain via a guide tube. The probe is held in the guide tube by a compression fitting. The submittal is therefore identical to 510(k) K010422 except for the inclusion of features related to incorporating a guide tube and compression fitting and except for changes in labeling related to model number and indications for use. In order to easily see new paragraphs or portions of a paragraph that have been altered from the prior ACT II, 510(k) K010422 submittal, new text has been changed to this color for ease of locating new material.

The modification incorporates a guide tube and compression fitting in the bolt cap to allow the insertion and retention of a probe .7 to .9 mm (028 to .036") in diameter. The device is named ACT II MP. The MP stands for multi-parameter and denotes a multi-parameter device capable of measuring ICP and a second parameter such as tissue pO_2.

The MP system is essentially unchanged from ACT II 510(k) K010422 other than placing a guide tube in the cap and incorporating certain cap and bolt changes that provide proper alignment of the guide tube and drainage catheter. There are two caps, the cap that comes on the bolt from the factory and the drainage catheter cap that comes with the drainage catheter from the factory. Both caps provide a guide tube that directs the path of a probe inserted through the cap/bolt. The guide tube does not enter the brain. It simply guides an inserted probe to a point above the dura. The cap and guide tube are similar in function to the introducer kits described in predicate device 510(k) K002765- by Licox. The rest of the device is similar in function and features as predicate device 510(k) K010422 - ACT II by InnerSpace

For ease of reading, ACT II will be referred to throughout as the **basic** system and the MP version of ACT II, as the **MP**.

2.2 ICP Monitoring Device Name

2.2.1	Trade name	ACT II MP ICP Monitoring System
2.2.2	Common name	Intracranial Pressure Monitoring Device
2.2.2	Classification name	Intracranial Pressure Monitoring Device CFR 882.1620 (84GWM)

2.3 Ventricular Catheter Name

2.3.1	Trade name	ACT II MP Ventricular Catheter
2.3.2	Common name	Ventricular Catheter
2.3.3	Classification name	Ventricular Catheter CFR 882.4100 (84HCA)

2.4 Equivalent device

The ACT II MP ICP Monitoring System is a substantially equivalent device to the ACT II ICP Monitoring System 510(k) K010422 by InnerSpace and to the introducer kits described in 510(k) K002765 by Licox.

2.5 Description of the ICP Monitoring Device

The ICP monitor uses a bolt anchored in the skull. The bolt holds an air-column catheter with a flaccid bladder on the distal end. The proximal end of the catheter is attached to a pressure transducer placed in the distal end of a standard cable. The cable can be attached directly to any patient monitor. The ICP monitoring technology is based on Boyle's law. The bladder volume changes to accommodate $P_1V_1=P_2V_2$. The pressure in the bladder, catheter and transducer thereby mirrors that of ICP. The air required to activate the bladder is introduced into the bladder when a piston on the proximal end of the catheter is joined to a cylinder on the transducer housing. The bladder air is replaced once per shift by removing and replacing the transducer housing on the piston

2.6 Description of the probe guide

A probe guide is incorporated into the cap placed on the bolt at the factory and into the cap that accompanies the drainage catheter. The guides direct the path of a probe inserted through the cap/bolt. The guide tube does not enter the brain but stops just above the drill hole. Both caps provide a compression fitting that secures and seals the probe to the cap.

2.7 Description of the Ventricular Catheter

The catheter is a single lumen catheter. A preloaded stylet is used for catheter insertion and placement. A luer connector is provided to connect the catheter to a standard CSF collection system.

The bolt provides an access port through which a ventricular catheter can be introduced if drainage is needed. Should drainage of CSF be indicated, the top cap of the bolt is removed and the ACT II Ventricular Catheter is inserted into a ventricle. Once the catheter is in place, a preinstalled elastomeric sleeve and compression cap are moved down the catheter to the bolt. The cap compresses the sleeve against the bolt and catheter anchors the catheter in place.

The intent of the **basic** system design is to provide a minimally invasive ICP monitoring device to which a drainage capability can be added if needed. The intent of the MP system is to add a probe guide to the **basic** system. The probe guide can be seen in the graphics following the text of **Section 5**. For purposes of clarity, the graphics portraying the approved predicate device will be identified as the **basic** device. The graphics of the new device will be identified to as the **MP** device. A catheter capable of measuring another parameter, such as tissue oxygen, that may be inserted into the brain through the cap will be referred to as a **probe.**

Pressure sensor

The pressure sensor, its mounting and use are unchanged

Transducer housing

The housing that engages the bolt is unchanged.

2.7 Intended Use of the Device

The device is to be used in patients who require continuous ICP monitoring, who may require drainage of CSF and who may require monitoring of a second parameter such as tissue oxygen.

2.8 Device Characteristics vs. Predicate Device

The characteristics of the **Basic** device vs. the **MP** device are shown in Table 1.

Table 1

Characteristic	**ACT II Basic**	**ACT II MP**	**Comment**
Bolt diameter	.250"	. 250"	No change
Skull Attachment	Ribs	Ribs	No change
Pressure sensor OD	1.5 mm	1.5 mm	No change
Pressure catheter bladder mount	PVC	PVC	No change
Pressure catheter bladder	Butyl	Butyl	No change
Microbore tube material in brain (housed within bladder)	Polyimide	Polyimide	No change
Depth of bladder in brain	1.3 cm	1.3 cm	No change
Probe guide (not in the brain)	N/A	Stainless steel	**New feature**
Ventricular Catheter OD	2.5 mm	2.5 mm	No change
Ventricular Catheter ID	1.5 mm	1.5 mm	No change.
Catheter material	Tecoflex EG-80A	Tecoflex EG-80A	No change
Depth of ventricular catheter in brain	6-8 cm	6-8 cm	No change
Bacteria barrier	Betadine on bolt/skull	Betadine on bolt/skull	No change
Probe catheter diameter	N/A	0.7 to 0.9 mm	See Note

Note: The introducer kit in predicate device 510(k) K002765 receives an oxygen probe 0.8 mm diameter.

2.9 Animal and Laboratory testing:

- The subject device meets AAMI performance standards.
- Animal test data of the subject device vs. a ventricular catheter shows the device faithfully follows the ventricular pressure and waveform and that the bolt is securely anchored in the skull.

The biocompatibility of the **ACT II ICP Monitoring System** related to the bolt was tested per ISO 10993-1-1994 Biological Evaluation of Medical Devices – Part 1: Guidance on the Selection of Tests and the FDA General Program Memorandum No. G95-1. The material used in the catheter is Tecoflex EG-80A.

Conclusion

The **ACT II MP ICP Monitoring System**, in combination with the **ISM –3000** series cable, and the **ACT II MP Ventricular Catheter** are equivalent to the predicate devices (510(k) K010422 and 510(k) K002765) because:

Intended Use

The system has the same basic intended use, namely to sense intracranial pressure and drain CSF if needed. The **MP** feature accommodates the introduction of a probe to monitor an additional parameter if the doctor deems the resultant data beneficial to patient management.

Safety

Laboratory testing has shown that the **ACT II MP ICP Monitoring System**, the **ACT II MP Ventricular Catheter** and the **ISM –3000** series cable or pigtail are safe in the following areas:

- Mechanical integrity Laboratory testing and basic design assure that no parts will come loose and be left in the patient. The interference rib design provides a secure attachment to the skull. The compression fitting is capable of securing a probe and providing an effective seal.
- Biocompatibility The materials used in the **ACT II MP ICP Monitoring System** and **ACT II MP Ventricular Catheter** that come in contact with the body are the same as those used in the **ACT II ICP Monitoring System** and **ACT II Ventricular Catheter.**

Effectiveness

- Accuracy The ICP monitoring system meets AAMI standards for accuracy and performance.
- Ease of use The catheter is mounted in a bolt, as is the predicate device ICP device. A probe introduced into the bolt is held in place by a compression device in the same manner as the predicate probe introduction device.
- Set up There is no need to precondition or calibrate the system beyond the normal zeroing of the transducer. The transducer connects directly to any patient monitor.
- Operating life The IFU requires that the air in the bladder be replaced every shift. The air is replaced by removing (disconnecting) and replacing (reconnecting) the transducer to the piston.
- Trouble-shooting Unlike other in-situ systems, the transducer function and patient monitor zero can be checked at any time.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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MAR 8 2002

Mr. Don Bobo
Innerspace
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Suite A
Santa Ana, California 92705

Re: K013005
Trade/Device Name: ACT II MP ICP Monitoring System
Regulation Number: 21 CFR 882.4100
Regulation Name: Intracranial Pressure Monitoring Devices
Regulatory Class: Class II
Product Code: HCA
Dated: January 14, 2002
Received: January 23, 2002

Dear Mr. Bobo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K013005

Device Name ACT II MP ICP Monitoring system

Indications For Use

Indications The use of the ACT II MP Monitoring System by a qualified neurosurgeon is indicated when direct measurement of intracranial pressure in parenchyma is clinically important and when the patient may require CSF drainage in the course of their care or when data from a second parameter may be deemed useful in optimum patient management.

Please do not write below this line

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X Or Over-The Counter Use ____
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013005